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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,508	05/10/2001	Roland Cherif Cherif Cheikh	BET01/0233	2278

466 7590 11/02/2006

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EXAMINER

DESANTO, MATTHEW F

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 11/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/787,508

Applicant(s)

CHERIF CHEIKH ET AL.

Examiner

Matthew F. DeSanto

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 45-47 and 49-89 is/are pending in the application.
- 4a) Of the above claim(s) 56 and 58-86 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 45-47, 49-55, 57 and 87-89 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 45, 46, 47, 49, 50, 51, 52, 87, 88 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamashita (55-7352).

Yamashita discloses a syringe with a reservoir, a piston, a base, needle, and wherein the needle is fastened to the reservoir by direct application of the element forming the reservoir against the base by a support or casing (13) which houses said element forming the reservoir. (Figures 1, 4 and 5 and entire reference).

As to claim 45, wherein said element forming the reservoir provides mechanical resistance of the syringe. (Figures 1, 4, 5 and entire reference).

2. Claims 45, 47, 49, 51, 52, and 87-89 are rejected under 35 U.S.C. 102(b) as being anticipated by W. Roos (USPN 2,537,550).

W. Roos discloses a syringe with a hollow element (d) including a reservoir, a piston, a base, needle (b), and wherein the needle is fastened to the reservoir by direct

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application of the element forming the reservoir against the base by a support or casing (a) which houses said element forming the reservoir (Figures 1, 2 and entire reference).

3. Claim 45-47, 49 - 52, and 87-89 are rejected under 35 U.S.C. 102(e) as being anticipated by DeChellis et al. (USPN 4,921,486)

4. DeChellis et al. discloses a syringe with a reservoir, a piston, a base, needle, and wherein the needle is fastened to the reservoir by direct application of the element forming the reservoir against the base by a support or casing which houses said element forming the reservoir. The needle is in a fixed engagement in figure 1 and 2. (Figures 1, 2 and entire reference)

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 53-55, and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamashita as applied to the claims above, and further in view of Higashikawa (USPN 5704918).

With regard to claims 53-55, Yamashita meets the claim limitations as described above but fails to include the claimed dimensions. At the time of the invention, it would have been obvious to construct the device from the claimed dimensions since the Federal Circuit has held, where the only difference between the prior art and the claims was a recitation of relative dimension/size/proportion of the claimed device and a device

having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.

With regard to claim 57;

Yamashita disclosed the claimed invention but fails to disclose wherein the tubular reservoir has more than two tubes.

Higashikawa disclosed an adjustable dispensing syringe with an outer cast, and two inner tubes that form inside the reservoir.

At the time of the invention it would have been obvious for a person of ordinary skill in the art to combine the disclosed invention of Yamashita with the teachings of Higashikawa because it is well known in the art to use two tubes when combining different agents being injected into the body, especially when one agent is a liquid and the other agent is a solid material.

### ***Response to Arguments***

7. Applicant's arguments filed 6/06/06 have been fully considered and some are persuasive and some are not persuasive.
8. The applicant argues that Yamashita (JP-55-73352) does not show the needle in direct contact with the hollow element and that the casing member does not provide axially force to strengthen the hollow element.
9. The examiner disagrees with this interpretation, since the examiner is interpreting element 13 to be the base with the needle 15 which are integral. There is direct contact prior to the distal terminus of the hollow element of the prior art. The section near the end of the hollow element is in direct contact with the base of the needle, which

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can be seen in the figure. With regards to the casing member not providing support, this is the reason for the thread, to provide support and strength to the syringe and the whole apparatus. The examiner would also like to note that this language is functional language and the casing member has the capability to perform the function claimed, since the structure is the same. According to the MPEP there must be a structural difference between the prior art and the claimed invention in order to receive a patent (MPEP 2114). The applicant is arguing functional language and fails to disclose the structural difference between the prior art and the applicant's invention. The examiner would like further clarification on what structure causes the causing force, since the examiner doesn't understand how the prior art casing fails to reinforce and strengthen the hollow element and base. The examiner interpretation is that the casing or outer structure is what is providing the necessary means and support for the inner hollow element. This is the same structure in the prior art. The outer element (17b) encloses the needle structure and hollow element, therefore allowing the outer element to provide support and ultimately lead to casing axially force said directly against the base for strengthening said hollow element, especially when fluid is being dispensed through the needle.

10. With regards to the reservoir prefilled with a semi-solid preparation, it is well known that syringe can be prefilled with various preparations, as seen in the other prior art. The applicant is relying on the abstract and not the entire disclosed invention, which further supports the rejection over the claimed invention.

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11. With regards to Roos, the applicant argues that element b cannot be a needle and that the "needle" is not fastened to the hollow element of the casing. The examiner disagrees with both interpretations of the prior art. Element b is pointed and slender, thus resembles and reads on the definition of a needle. A needle doesn't need to be sharp. The device can also be used to inject fluid through the skin if enough pressure is applied thus reading on the **intended use** limitation of using the syringe for parenteral injection. The examiner disagrees with regards to the interpretation of Roos with the limitation of a continuous external surface. The examiner agrees that Roos doesn't disclose a continuous external surface in the longitudinal direction, but this is not the exacted claimed language. Therefore the examiner can interpret Roos to have a continuous external surface at the front portion of the hollow element in a circular direction as opposed to the longitudinal direction, thus meeting the claim limitation.

12. With regards to Dechallis the examiner disagrees with the applicant's interpretation of this reference. The needle is fixedly engaged prior to injection and during injection. Therefore, if the syringe is never or only partially used the needle would still be fixedly engaged between the reservoir and the housing. The examiner would like further clarification on what structure causes the causing force, since the examiner doesn't understand how the prior art casing fails to reinforce and strengthen the hollow element and base. The examiner interpretation is that the casing or outer structure is what is providing the necessary means and support for the inner hollow element. This is the same structure in the prior art. The outer element (40) encloses the needle structure and hollow element, therefore allowing the outer element to provide support

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and ultimate lead to casing axially force said directly against the base for strengthening said hollow element, especially when fluid is being dispensed through the needle.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F. DeSanto whose telephone number is 571-272-4957. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick LUCCHESI can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Matthew DeSanto  
Art Unit 3763  
October 30, 2006